PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P1187 PCT	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US 03/32441	International filing date *(day/month/year)* 14.10.2003	Priority date *(day/month/year)* 22.10.2002
International Patent Classification (IPC) or both national classification and IPC B05D1/00		
Applicant MEDTRONIC VASCULAR INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
19.05.2004	07.12.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Fayos, C Telephone No. +49 89 2399-2180

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US 03/32441

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-10 as originally filed

Claims, Numbers

1-25 received on 22.07.2004 with letter of 07.07.2004

Drawings, Sheets

1/7-7/7 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	24-25
	No:	Claims	1-23
Inventive step (IS)	Yes:	Claims	-
	No:	Claims	1-25
Industrial applicability (IA)	Yes:	Claims	1-25
	No:	Claims	-

2. Citations and explanations

   see separate sheet

Preliminary note:
The newly filed claims 1-25 only amount to editorial changes with no real changes having regard to the subject matter claimed.

The current assessment is based on the assumption that all claims enjoy priority rights from the filing date of the priority document. It the later turns out that is not correct, the document D1 cited in the international search report could become relevant.

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1- Reference is made to the following documents:
D1: EP-A-1329230
D2: US-A1-2002051730
D3: US-A1-2002133183
D4: WO-A-9856312
D5: US-A-6096070
D6: WO-A-0243619
D7: WO-A-02074194
D8: WO-A-0187372
D9: EP-A-0701802
D10: US-A-6129705

NOVELTY - Art. 33 (1) and (2) PCT

2- Claims 1-23 lack novelty:

2.1- D2: Drug coated stent useful for the local delivery of drug/drug combinations. The type of coating depends on the type of drug (rapamycin and polymer (outer surface) in combination with heparin (inner surface)). The coating may be uniform or not and continuous or discontinuous.
D2 is novelty destroying for the subject matter of claims 1-23.

2.2- D3: Coated stents. Therapeutic drugs, agents or compounds may be mixed with the biocompatible materials and affixed to at least a portion of the stent (rapamycin and heparin).
D3 is novelty destroying for the subject matter of claims 1-23.

2.3- D4: Coated stents: two or more coating layers of polymeric compositions (inner layer, outer layer). The outer layer may be used as drug delivery system. The inner layer may contain a drug too. The stent can have multiple layers of different polymers with the same or different drugs.
D4 is novelty destroying for the subject matter of claims 6-22.

2.4- D5: Coated stent: two or more layers of different bioactive materials. The same bioactive material will generally not be deposited on the different surfaces of the device within the same layer (i.e. each surface of the device carries different bioactive materials).
D5 is novelty destroying for the subject matter of claims 1-23.

2.5- D6: A portion of an inner surface or an outer surface of a stent is coated with a material containing a polymer and a biologically active material.. Inner and outer portion of the medical device can be coated with different materials. Also, there can be more than one coating on a surface and the entire surface of the stent is not necessarily coated.
D6 is novelty destroying for the subject matter of claims 1-23.

2.6- D7: Medicated stent (S1) with a coating comprising a primer layer (a) comprising a first composition (a1) of at least one polymer, and a drug reservoir layer (b) comprising a second composition (b1) of at least one polymer and active agent(s). One or more drug carrier polymer layers can be applied. Different drugs contained within different layers.

D8: Two coating layers: one with polymer and dexomethasone and the other with rapamycin and polymer.

D9: Stent coated with polymer containing a drug.

D10: Balloon, catheter and coated stent.

INVENTIVE STEP - Art. 33 (1) and (3) PCT

3- No inventive step can be acknowledged for the subject matter of claims 1-23, which

lack novelty.

3.1- The features of claims 24-25 are merely some of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.

INDUSTRIAL APPLICABILITY - Art. 33 (1) and (4) PCT

4- Claims 1-25 appear to be industrially applicable.